REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. §112, are respectfully requested in light of the following remarks.

STATUS OF CLAIMS

Claims 1, 3-16, 20, 21, 23, 26, 27 and 29-38 are now in this application. Claim 1 has been amended. Claim 28 has been cancelled as redundant in light of the amendment to Claim 1, the dependency of Claim 29 has been accordingly amended and Claims 36-38 have been added.

Support for the amendments to Claim 1 are found at least on page 10, lines 22-26 and page 11, lines 32-36 of the original specification. Support for new Claim 36 is located at least on page 11, lines 32-33 of the specification (supporting "fatty acid ester derivative of alanine") read in conjunction with page 12, lines 24-30 of the specification (showing that these derivatives are ones in which the acid function is esterified (L-alanine methyl ester, L-alanine ethyl ester, etc.) and the amine function is substituted with a fatty acid chain (N-lauroyl, N-stearoyl). Claims 37 and 38 are also supported by page 12, lines 24-30 of the specification. Thus, no new matter has been added.

DRAWINGS

The acceptance of the drawings is noted, with appreciation.

FOREIGN PRIORITY CLAIM

The Examiner has acknowledged the claim for foreign priority. Applicants request also the Examiner's acknowledgment of receipt of a copy of the certified copy of the French priority document from the International Bureau in this national stage application.

INFORMATION DISCLOSURE STATEMENT

Applicants thank the Examiner for considering the Information Disclosure Statement and returning an initialed copy of their Form PTO-1449.

CLAIM REJECTIONS - 35 U.S.C. §103

Claims 1, 3-16, 20-21, 23 and 26-35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fanara et al. U.S. Patent No. 6,464,987 in view of Luo et al., *Chem. Commun.* 2001, 1556-1557. Applicants submit that all of the claims now in this application are free of the obviousness rejection.

Fanara et al. teach a fluid pharmaceutical composition having the property of gelling instantaneously in the presence of an aqueous phase. Upon contact with a mucous membrane, a gel forms under the skin or in the muscle, and the medicinal product may diffuse or be released from the gel. The composition comprises phospholipids as the organogelling substance. Fanara et al. do not teach or suggest amino acid derivatives as organogelling substances.

Luo et al. teach self-assembled organogels formed by mono-chain alanine derivatives with the organic liquids CCl_4, benzene, toluene, o-xylene, mesitylene, 1,1,2,2-tetrachloroethane and a few others; see Table 1 of Luo et al. However, all of

these liquids are hydrocarbons which are unsuitable for administration to an animal body. Luo et al. do not teach organogels formed with any solvents suitable for administration to a patient.

Moreover, Luo et al. cool their mixtures to 20°C to form their organogels. They do not teach or suggest that their gels would remain stable at about 37°C., which is the body temperature of a patient. On the contrary, Luo et al. teach that on reheating, the physical gelation is reversible (page 1557, right column, Notes, final sentence). This means that on heating, the gel can turn into a liquid. To go from Luo et al.'s 20°C (stable gel) to 37°C (body temperature), requires heating. Therefore, knowing that the gels of Luo et al. are stable at 20°C but when heated are liquefied, one of ordinary skill would not have an expectation that Luo et al.'s gels would remain stable at the significantly higher body temperature of 37°C.

Further, Luo et al.'s compositions gelify without the presence of water, while Fanara et al.'s compositions absolutely require the presence of an aqueous phase to gelify. Therefore, the mechanism of gelification of the two references are totally different. Consequently, one of ordinary skill in the art would not be motivated to even try to combine the compositions of the two references.

It is also pointed out that the Fanara et al. reference is silent as to the use of any gelling agents other than those containing phospholipids. And as the C.C.P.A. succinctly stated in its decision *In re Burt and Walter*, 148 U.S.P.Q. 548 (1966), "Silence in a reference is hardly a proper substitute for an adequate disclosure of facts from which a conclusion of obviousness may justifiably follow." Moreover, there is nothing in the secondary reference, Luo et al., to suggest to one of ordinary skill in the art that Luo et al.'s alanine derivatives, which form organogels at the low

temperature of 20°C in the absence of water but in the presence of organic liquids which are not pharmaceutically acceptable, would be useful in Fanara et al.'s compositions or in those of applicants.

In view of the foregoing, it is submitted that the record 35 U.S.C. §103 rejection is untenable against any of the claims now in this application. Further, favorable action in the form of a Notice of Allowance is believed to be next in order and is earnestly solicited.

Respectfully submitted,

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